8W

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,248	12/10/2001	John P. Alsobrook II	21402-218 (Cura-518)	4403

7590 07/28/2004

Ivor R. Elrifi
MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,248	ALSOBROOK ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-49 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-22. Claims 1-4, 38, 41 are drawn to 22 distinct polypeptides, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 530, subclass 350+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 23-44. Claims 5-14, 39, 42 are drawn to 22 distinct polynucleotides, SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 536, subclass 23.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a single polynucleotide sequence, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 45-66. Claims 15-17 are drawn to 22 distinct antibodies which bind to 22 distinct amino acid sequences , wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified

in Class 530, subclass 387.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a single antibody to a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 67-88. Claim 18 is drawn to 22 distinct methods of determining the presence of 22 distinct polypeptides with antibodies which bind to 22 distinct amino acid sequences , wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the presence of a single polypeptide, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 89-110. Claim 18 is drawn to 22 distinct methods of quantifying 22 distinct polypeptides with antibodies which bind to 22 distinct amino acid sequences , wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the presence of a single polypeptide, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 111-132. Claims 19-21 are drawn to 22 distinct methods of determining the presence of 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 6. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the presence of a single polynucleotide, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 133-154. Claims 19-21 are drawn to 22 distinct methods of quantifying 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 6. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of quantifying a single polynucleotide, and variants thereof. Applicant is required to elect a single invention for examination.

3. It is noted that the claims of the instant application have been determined to include linking claims. Claim 22 links Groups 155-196. The

restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 22. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 155-174. Claims 22-23 are drawn to 22 distinct methods of identifying an agent/a cellular receptor that binds to one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 4. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of identifying an agent/a cellular receptor that binds to a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 175-196. Claims 22-23 are drawn to 22 distinct methods of identifying an agent/a downstream effecter that binds to one of 22

distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 4. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of identifying an agent/a downstream effecter that binds to a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

4. It is noted that the claims of the instant application have been determined to include linking claims. Claim 24 links Groups 197-240. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 24. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 197-218. Claim 24 is drawn to 22 distinct methods of identifying an agent modulates the expression of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, wherein the modulation is not at the level of the polynucleotide classified in Class 435, subclass 4, 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of identifying an agent that modulates the expression of a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

Groups 218-240. Claims 24-25 are drawn to 22 distinct methods of identifying an agent that modulates the activity of one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 435, subclass 4, 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of identifying an agent that modulates the activity of a single amino acid sequence, and variants thereof . Applicant is required to elect a single invention for examination.

Groups 241-262. Claim 24 is drawn to 22 distinct methods of identifying an agent that modulates the expression of one of 22 distinct the amino acid sequences of SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof at the polynucleotide level, classified in Class 435,

subclass 6. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of identifying an agent modulates the expression of a single amino acid sequence, and variants thereof. Applicant is required to elect a single invention for examination.

5. It is noted that the claims of the instant application have been determined to include linking claims. Claim 26 links Groups 263-350. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 26. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 263-284. Claims 26, 27, 29, 48 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder/cardiomyopathy comprising administering one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38

40, 42, 44 and variants thereof classified in Class 512, subclass 2+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder/cardiomyopathy with a single distinct polypeptide sequence. Applicant is required to elect a single invention for examination.

Groups 285-306. Claims 26, 27, 29, 48 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder/atherosclerosis comprising administering one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 512, subclass 2+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder/ atherosclerosis with a single distinct polypeptide sequence. Applicant is required to elect a single invention for examination.

Groups 307-328. Claims 26, 28, 29, 48 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein said disorder is related to cell signal processing comprising administering one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 512, subclass 2+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of

treating or preventing a NOVX-associated disorder wherein said disorder is related to cell signal processing with a single distinct polypeptide sequence. Applicant is required to elect a single invention for examination.

Groups 329-350. Claims 26, 28, 29, 48 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein said disorder is related to metabolic pathway modulation comprising administering one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 512, subclass 2+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder wherein said disorder is related to metabolic pathway modulation with a single distinct polypeptide sequence. Applicant is required to elect a single invention for examination.

6. It is noted that the claims of the instant application have been determined to include linking claims. Claim 30 links Groups 351-438. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking

claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 351-372. Claims 30, 31, 33 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder/cardiomyopathy comprising administering one of 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 536, subclass 23.1+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder/cardiomyopathy with a single distinct polynucleotide sequence. Applicant is required to elect a single invention for examination.

Groups 373-394. Claims 30, 31, 33 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder/atherosclerosis comprising administering one of 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof

wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 536, subclass 23.1+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder/atherosclerosis with a single distinct polynucleotide sequence. Applicant is required to elect a single invention for examination.

Groups 395-416. Claims 30, 32, 33 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein the disorder is related to cell signal processing comprising administering one of 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 536, subclass 23.1+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder wherein the disorder is related to cell signal processing with a single distinct polynucleotide sequence. Applicant is required to elect a single invention for examination.

Groups 417-438. Claims 30, 32, 33 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein the

disorder is related to metabolic pathway modulation comprising administering one of 22 distinct polynucleotides wherein said polynucleotides are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 536, subclass 23.1+. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder wherein the disorder is related to metabolic pathway modulation with a single distinct polynucleotide sequence. Applicant is required to elect a single invention for examination.

7. It is noted that the claims of the instant application have been determined to include linking claims. Claim 34 links Groups 439-504. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 34. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 439-460. Claims 34-35, 37, 49 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder/diabetes comprising administering one of 22 distinct antibodies to 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder/ diabetes with a single distinct antibody to a single distinct polypeptide. Applicant is required to elect a single invention for examination.

Groups 461-482. Claims 34, 36, 37, 49 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein the disorder is related to cell signal processing comprising administering one of 22 distinct antibodies to 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder wherein the disorder is related to cell signal processing comprising

administering one of 22 distinct antibodies to 22 distinct with a single distinct antibody to a single distinct polypeptide. Applicant is required to elect a single invention for examination.

Groups 483-504. Claims 34, 36, 37, 49 are drawn to 22 distinct methods of treating or preventing a NOVX-associated disorder wherein the disorder is related to metabolic pathway modulation comprising administering one of 22 distinct antibodies to 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of treating or preventing a NOVX-associated disorder wherein the disorder is related to metabolic pathway modulation comprising administering one of 22 distinct antibodies to 22 distinct with a single distinct antibody to a single distinct polypeptide. Applicant is required to elect a single invention for examination.

8. It is noted that the claims of the instant application have been determined to include linking claims. Claim 44 links Groups 505-548. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 505-526. Claim 44 is drawn to 22 distinct methods of determining the presence of a disease associated with altered levels of one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the presence of a disease associated with altered levels of a single polypeptide. Applicant is required to elect a single invention for examination.

Groups 505-526. Claim 44 is drawn to 22 distinct methods of determining the presence of a disease associated with altered levels of one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement

to elect an invention consisting of a method of determining the presence of a disease associated with altered levels of a single polypeptide. Applicant is required to elect a single invention for examination.

Groups 527-548. Claims 44, 45 are drawn to 22 distinct methods of determining a predisposition for a disease associated with altered levels of one of 22 distinct polypeptide sequences, wherein the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the predisposition for a disease associated with altered levels of a single polypeptide. Applicant is required to elect a single invention for examination.

9. It is noted that the claims of the instant application have been determined to include linking claims. Claim 46 links Groups 549-592. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), 46. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to

provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups 549-560. Claim 46 is drawn to 22 distinct methods of determining the presence of a disease associated with altered levels of one of 22 distinct polynucleotide sequences, wherein the polynucleotide sequences are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 536, subclass 23.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining the presence of a disease associated with altered levels of a single polynucleotide. Applicant is required to elect a single invention for examination.

Groups 571-592. Claims 46-47 are drawn to 22 distinct methods of determining predisposition to a disease associated with altered levels of one of 22 distinct polynucleotide sequences, wherein the polynucleotide sequences are SEQ ID NOS 1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27, 29, 31,33, 35, 37, 39, 41, 43 and variants thereof wherein said polynucleotides encode the amino acid sequences are SEQ ID NOS 2, 4,6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 31, 34, 36, 38 40, 42, 44 and variants thereof, classified in Class 536,

subclass 23.1. It is noted for Applicant's convenience that this is **not** an election of species requirement, but rather a requirement to elect an invention consisting of a method of determining predisposition to a disease associated with altered levels of a single polynucleotide. Applicant is required to elect a single invention for examination.

10. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-66 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 67-592 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1-22 and 67-110, 155-240, 263-350, 505-548 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as a method of making an antibody.

The inventions of Groups 23-44 and 111-154, 241-262, 351-438, 549-592 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially

different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as in the production of polypeptides.

The inventions of Groups 45-66 and 67-88, 439-504 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as in the production of anti-idiotypic antibodies.

The inventions of Groups 1-22 and 111-154, 241-262, 351-438, 549-592 are not at all related because the polypeptides of Groups 1-22 are not at all used in the methods of Groups 111-154, 241-262, 351-438, 549-592

The inventions of Groups 23-44 and 67-110, 155-240, 263-350, 505-548 are not at all related because the polynucleotide of Groups 23-44 is not at all used in the methods of Groups 67-110, 155-240, 263-350, 505-548.

The inventions of Groups 45-66 and 111-154, 241-262, 351-438, 549-592 are not at all related because the antibodies of Groups 45-66 are not at all used in the methods of Groups 155-240, 263-350, 505-548.

11. Because these inventions are distinct for the reasons given above have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37

C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar, PhD
Primary Patent Examiner
July 22, 2004